

Laboratory Safety and Lessons Learned from the Ebola Response

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Clinical Laboratory Improvement Advisory Committee (CLIAC)

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Agenda

Laboratory Safety and Lessons Learned from the Ebola Response:
Dr. Nancy Cornish, Ms. Elizabeth Weirich

Laboratory Safety and Risk Assessment: Dr. Sheldon Campbell

NIOSH Industrial Hygienist-Safety Assessments: Dr. Nancy Burton

Public Health Laboratory Perspective: Dr. Michael Pentella

Long Term Issues for Clinical Laboratories

(Presented at last CLIAC meeting November 2014)

- How to assure that clinical laboratories are prepared for biological threats and emerging infectious diseases?
- How to assure the safety of laboratory instruments?
- How to assure compliance with standard laboratory precautions and the OSHA bloodborne standard?
- Who inspects laboratories for safety?

Laboratory Safety Gaps Identified During Rapid Ebola Preparedness (REP) Team Visits to US Hospitals

- October 2014-January 2015: CDC REP teams evaluated 55 hospitals for their capacity and preparedness to receive, identify and treat patients with suspected or confirmed Ebola virus disease
- **Results:**
 - Assumptions about laboratory safety and operations were being made but were not necessarily true
 - The safety gaps identified, ***present an opportunity*** to educate and improve safety and operations

Some Common Gaps in Laboratory Safety Identified

- Laboratory staff were not always conducting risk assessments, following OSHA's blood borne pathogens standard, or implementing safe work practices
- Laboratory instruments were not necessarily safe for operators
- Lack of communication between lab and clinical care
- Insufficient training in work practices and personal protective equipment (PPE) leading to:
 - *fear and lack of confidence among staff*
 - *reluctance to test patient specimens*

Problems Identified with Routine Testing of Persons Under Investigation (PUIs) in Clinical Laboratories- *which led to more fear*

- **Lack of data on safety of routine clinical laboratory procedures for Ebola specimens**
- **Some professional organizations recommended that laboratories limit testing in their regular clinical laboratories on PUIs for Ebola**
- **Some national reference laboratories requested that clients not submit specimens from PUIs for Ebola**
 - “Any laboratory testing requested on specimens from suspected Ebola patients should **not** be sent but held until results for Ebola testing are confirmed as negative by the CDC.”

How to assure that clinical laboratories are prepared for biological threats and emerging infectious diseases?

- Raise awareness of Laboratory Director responsibilities for providing a safe environment in which employees are protected from physical, chemical and biological hazards (CLIA regulations; 42 CFR Part 493.1407(e)(2) and 1445(e)(2)
 - *How?*
- Training and education of laboratory professionals to increase knowledge, skills and abilities necessary to ensure a safe working environment to include but not limited to;
 - Risk assessment
 - Personal protective equipment (PPE)
 - Safe work practices, including biosafety cabinets (BSC)

Risk assessment is the basis of a safety program

- **Responsible persons (Lab Director, biosafety officer, lab supervisor) should conduct risk assessments to :**
 - Determine potential for sprays, splashes, or aerosols
 - Adjust engineering controls, work practices, or personal protective equipment to protect skin, eyes, mucous membranes
- **Risk assessments are not always performed due to lack of knowledge**
 - How to do risk assessment?
 - Who to involve? Industrial hygienist, biomechanical engineering department, infection preventionist?
 - Lack of data and evidence base, or other reasons?

Risk assessment is the basis of a safety program

Risk Assessment is a process to:

- identify the hazards (agent, procedures and staff)
- evaluate the risks
- determine controls
- implement controls
- evaluate/review



Personal Protective Equipment (PPE)

- Is it appropriate for the activity? It depends on the risk assessment
- PPE will vary depending on:
 - what is being done (activities)
 - where it is being done (lab vs. patient room)
 - capabilities of the user
- Removing PPE is a risk-where, how, what sequence?
- Are staff *trained and comfortable*?
- Have they practiced procedures with PPE on?

PPE

- **More is not always better-**
 - Limited visibility, mobility and potential heat stress
 - Ill-fitting PPE can cause distraction and reduced sensory perception
 - *Distraction can compromise safety*

PPE for Safe Specimen Collection

PPE for Management of Hospitalized Ebola Patients:

- 1 Single use, disposable face shield, surgical hood extending to shoulders, and N95 Respirator OR PAPR with a full face shield, helmet, or headpiece (not shown)
- 2 Single use, disposable, fluid-resistant or impermeable gown that extends to at least mid-calf OR coverall without integrated hood (not shown)
- 3 Two pairs of single use, disposable gloves w/ extended cuffs
- 4 Single use, disposable, fluid-resistant or impermeable apron that covers the torso to the level of the mid-calf (optional)
- 5 Single use, disposable, fluid-resistant or impermeable boot covers that extend to at least mid-calf



Proper Use of Biosafety Cabinet (BSC)

- Load cabinet only with necessary equipment and supplies
- Do not cover the grilles
- Move arms slowly and deliberately



Improper Use of Biosafety Cabinet

- BSCs have very specific airflow patterns
- Crowded BSC can interrupt proper airflow and compromise operator safety, seen on REP visits
 - Infectious particles can be pushed out into the breathing zone of operator
 - Front grilles are covered, too much equipment inside
- Staff must be trained on how to move in and out safely



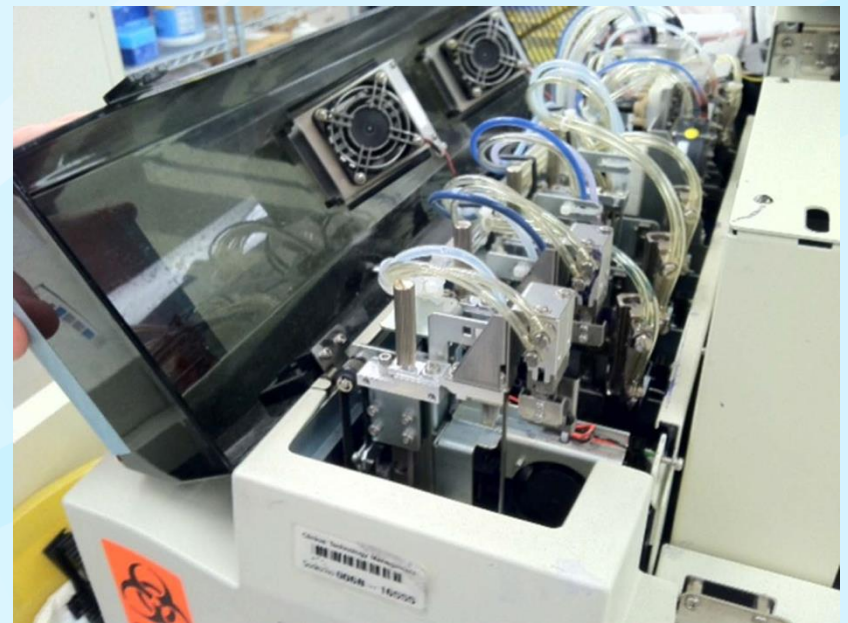
Problems Identified with Routine Testing of Persons Under Investigation in Clinical Laboratories

- *No organization evaluates or approves clinical laboratory instruments for safety*
- Lack of data on decontamination of automated laboratory instruments, racks, and plates
- Liquid waste disposal from instruments-open containers and released directly to drain



Problems Identified with Routine Testing of Persons Under Investigation in Clinical Laboratories

- Some instrument manufacturers have informed users that testing Ebola specimens would void warranties or prevent reuse of the instrument



GUIDELINES FOR SAFE WORK PRACTICES IN HUMAN AND ANIMAL MEDICAL DIAGNOSTIC LABORATORIES

Recommendations of a CDC-convened Blue Ribbon Panel

MMWR Supplement/Vol. 61, January 6, 2012

<http://www.cdc.gov/mmwr/preview/mmwrhtml/su6101a1.htm>

MMWR Blue Ribbon Biosafety Panel; List of Potential Aerosol and Droplet Generating Procedures

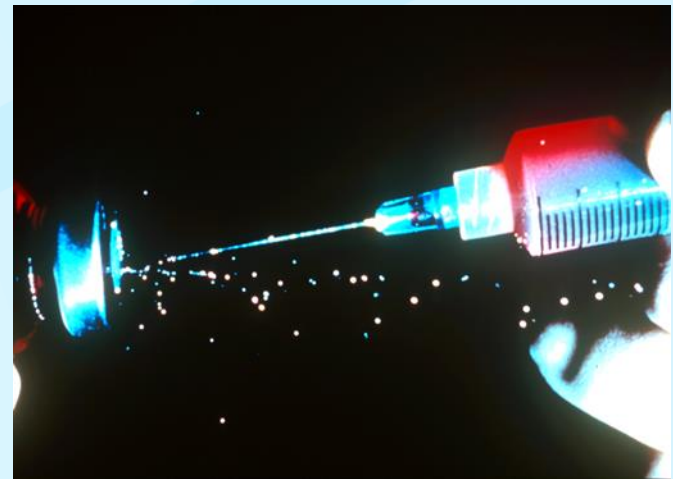
- Manipulating needles, syringes and sharps
- Manipulating inoculation needles, loops, pipettes
- Manipulating tissue and fluid specimens and cultures

Aerosols and Droplet Generation

- Procedures that impart energy to a microbial suspension
- Ubiquitous in laboratory procedures
- Usually undetected
- Thought to be major cause of laboratory acquired infections (LAIs)



Mixing test tube contents on a vortex



Extracting blood from a bottle

2007 GUIDELINE FOR ISOLATION PRECAUTIONS: PREVENTING TRANSMISSION OF INFECTIOUS AGENTS IN HEALTHCARE SETTINGS

**From the Healthcare Infection Control Practices Advisory
Committee (HICPAC)**

<http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>

**These guidelines are based on literature review and an
“evidence base” collected over time**

PRIMARY ROUTES OF INFECTIOUS DISEASE TRANSMISSION

Contact, Droplet and Airborne
Definitions

Contact Transmission

- **Direct:** microorganisms are transferred from one infected person to other person without a *contaminated* intermediate object or person through non-intact skin (cuts, abrasions, dermatitis, chapped skin, scratches etc.)
- **Indirect:** transfer of infectious agent through a contaminated intermediate object or person (hands of Healthcare personnel, patient care devices such as thermometers, stethoscopes, shared toys, inadequately cleaned instruments, soiled garments or surgical gowns)

Examples of Agents Which Are Mainly Transmitted via Contact

- Herpes simplex
- Mites (Scabies)
- VRE
- MRSA
- *C. difficile*
- And others as well as infectious agents which have multiple routes of transmission

Droplet Transmission

- A form of contact transmission with the addition of respiratory droplets traveling directly from the respiratory tract of the infected person to susceptible mucosal surfaces of the recipient; eyes/conjunctiva, nasal mucosa and mouth
- Traditionally Droplet size considered $> 5 \mu\text{m}$
- Respiratory droplets occur when talking, coughing, sneezing or during procedures such as tracheal suctioning, endotracheal intubation
- Organisms transmitted by the droplet route do not remain infective over long distances and therefore do not require special air handling and ventilation

<http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>

Respiratory Droplet Production During Sneezing



Public Health Image Library; phil.cdc.gov

Droplet Transmission ²

- **Maximum distance for droplet transmission is currently unresolved, more studies are needed**
- **Generally travel of droplets through air over short distances**
 - Historically thought to be \leq 3 feet
 - Specific studies of SARS and Smallpox, 6 foot distance
- **A distance of 3 feet around patient is an example of a short distance but is not sole criterion for deciding when to wear a mask**
- **In general a prudent choice may be to wear a mask when 6 to 10 feet from the patient. Esp. if exposure to highly virulent pathogens likely**

Examples of Infectious Agents Transmitted via Droplets

- *B. pertussis*
- Influenza virus
- Adenovirus
- Rhinovirus
- *M. pneumoniae*
- SARS-associated coronavirus (SARS-CoV)
- group A strep
- *N. meningitidis*
- RSV is “droplet plus contact” but contact is more common route of infection

<http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>

Airborne Transmission

- Very small particles “droplet nuclei” remain infectious and suspended in air for extended periods of time
- Suspended Droplet nuclei undergo desiccation and air currents can disperse droplet nuclei over distances
- When inhaled they enter respiratory tract and can cause infection
- Only occurs with infectious agents which are capable of surviving and retaining infectivity for relatively long periods of time
- Can be inhaled by susceptible individuals who have not face to face contact or been in the same room with the infected person

Airborne Transmission

- **“Droplet nuclei” size traditionally defined as $\leq 5 \mu\text{m}$ based on Tuberculosis pathogenesis however not generalizable to other infectious diseases with airborne route of transmission**
- **Observations of particle dynamics reveal that droplets of $30 \mu\text{m}$ can also float in the air for periods of time**
- **NIOSH certified N95 masks or higher level respirator is recommended**
- **Negative air flow rooms required to contain and remove the infectious agent**
 - Patient is placed under Airborne precautions in a airborne infection isolation room (AIIR)

Examples of Infectious Agents Transmitted via Airborne Transmission

- *Mycobacterium tuberculosis*
- Rubeola virus (measles)
- Varicella zoster virus (chickenpox)
- Variola virus (smallpox) published data suggests possibility that may be transmitted over long distances through air under unusual circumstances however contact and droplet are the more frequent routes of transmission
- Questions and issues concerning *short distance airborne transmission* with SARS, monkey pox, avian influenza, endotracheal intubation, vomitus and fecal material

<http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>

List of Occupational Health Infectious Diseases and Routes of Exposure

- Routinely transmitted by **contact or body-fluid** exposures: hepatitis B, hepatitis C, human immunodeficiency virus (HIV) infection, rabies, vaccinia (**Ebola**)
- Routinely transmitted through **aerosolized airborne means**: measles, tuberculosis, and varicella disease
- Routinely transmitted through **aerosolized droplet means**: avian influenza, diphtheria, meningococcal disease, mumps, pneumonic plague, rubella, SARS-CoV, smallpox, and viral hemorrhagic fevers.

How To Assure the Safety Of Laboratory Instruments

- **Design of instruments to keep operator safe**
 - Need closed instrument systems and/or engineering controls to contain aerosols generated by manipulation of patient specimens
 - Collaborate with FDA and Manufacturers?
- **Liquid waste generated by instruments needs to be disposed of safely in order to avoid human exposure**
 - Collaborate with FDA and Manufacturers and EPA?
- **Decontamination of instruments needs to be adequate and considered as part of the design of the instrument**
 - CDC is aware of the challenges that laboratories and their institutions face when decontamination instructions are not provided in the operator's manuals and is in consultation with FDA and the manufacturers to resolve these issues

How To Monitor, Evaluate and Assure Continuous Improvement in Laboratory Safety?

■ Training and Education

- Include laboratory safety as part of curriculum for undergraduate and graduate programs (medical technologists, pathology residents, medical students)
- Education of clinical care and laboratory staff
 - Different safety issues and PPE requirements-lab handles patient specimens but clinical staff directly handles patients

How To Monitor, Evaluate and Assure Continuous Improvement in Laboratory Safety?

Education of clinical care and laboratory staff (cont)

- Education of Infection Prevention personnel about:
 - different PPE requirements in laboratory and
 - engineering controls available and used in laboratory (biosafety cabinets, splash shields and “closed” instrumentation)
- Education of Laboratorians on how working with patients is different than working with patients’ samples
- CDC is working on training videos, work instructions and on-line modules for PPE, BSC, and Conducting Risk Assessments

How To Monitor, Evaluate and Assure Continuous Improvement in Laboratory Safety?

■ Work with partners?

- IDSA, SHEA, ASM, APIC, HICPAC, ASCP, APHL, CAP, others?
- Accrediting agencies
- Federal agencies:
 - NIOSH, FDA, EPA, OSHA, others?
- Cooperative agreements
 - PHL and Biosafety competencies
 - Epidemiology and Laboratory Capacity- Overarching biosafety committees/biosafety officers
 - Laboratory Biosafety for Ebola And Other Infectious Diseases



Workforce Competencies for Public Health Laboratories

■ Publication – MMWR June 2015

- Builds on previous MMWR biosafety competencies published April 15, 2011 (Structured differently with a focus on tasks)

■ Purpose:

- Provide a comprehensive set of nationally-vetted competencies for Public Health Laboratories and can also be used for clinical laboratories
- Serve as a foundation for a standardized system of laboratory workforce competencies
- Identify knowledge, skills, and abilities
- Provide several tools- to be released with the Competencies
 - Focused on Emergency Management & Response & Safety domains

Report-Lab Acquired Infections and Exposures

- Long recognized that there is no reporting system for lab acquired infections (LAIs)
- Trans Federal Task Force (2009) and Blue Ribbon Panel (2011) made recommendations to develop and implement a voluntary, non-punitive reporting system
 - Recommendation published in MMWR January 2012
- “Report-LAI” to be used to identify safety issues and training gaps in order to help reduce LAIs
- “Report-LAI” is currently in HHS clearance
- How can we help in making this available for clinical laboratory use?

Joint Project of CDC, NIH, and FDA

Report laboratory-acquired infections here!

Report-LAI is a website dedicated to the anonymous reporting of laboratory incidents that may result in a laboratory-acquired infection. As a joint project of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), this website's goal is to provide an easy and secure means of collecting data that can be analyzed to help you make your workplace safer.

In addition to being able to enter data about incidents in biological laboratories, site visitors will have full standardized reports generated from all data entered here.

Report-LAI is a simple, voluntary and anonymous reporting system. At no time will your information be shared by any other means that will identify you.

UNDER DEVELOPMENT



Our Mission

Laboratory biosafety is in everyone's best interest. The more we know about accidents, exposures to potentially infectious agents, any resulting laboratory-acquired infections, and patient outcomes, the better prepared we will be to respond to situations appropriately.

[Click here to read more.](#)



About the Joint Project

During revision of the CDC/NIH publication entitled *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), it was necessary to make decisions about inclusion of pertinent agent summary statements in the 5th Edition.

[Click here to read more.](#)



Why You Should Participate

Report-LAI-participating individuals or institutions cannot be identified, whether they have submitted an incident report or are viewing standardized reports, alerts, and safety trend analyses.

[Click here to read more.](#)

Glossary for Abbreviations

- IDSA; Infectious Disease Society of America
- SHEA; Society for Healthcare Epidemiology of America
- ASM; American Society for Microbiology
- APIC; Association of Professionals in Infection Control
- HICPAC; CDC Healthcare Infection Control Practices Advisory Committee
- ASCP; American Society of Clinical Pathology
- APHL; Association of Public Health Laboratories
- CAP; College of American Pathologists
- NIOSH; CDC National Institute for Occupational Safety and Health
- FDA; Food and Drug Administration
- EPA; Environmental Protection Agency
- OSHA; Occupational Safety and Health Administration

Accreditation Organizations/Exempt States Under CLIA

- **AABB; American Association of Blood Banks**
- **AALA; American Association for Laboratory Accreditation**
- **AOA; American Osteopathic Association**
- **ASHI; American Society for Histocompatibility and Immunogenetics**
- **COLA**
- **CAP; College of American Pathologists**
- **Joint Commission**
- **Exempt states; New York and Washington**



For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333

Telephone: 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348

Visit: www.cdc.gov | Contact CDC at: 1-800-CDC-INFO or www.cdc.gov/info

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.